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| 09/973,109 | 10/09/2001 | Roger J. Greenwald | ML-0492DIV | 6851 |

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EXAMINER

FINEMAN, LEE A

ART UNIT

PAPER NUMBER

2872

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,109

Applicant(s)

GREENWALD ET AL.

Examiner

Lee Fineman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 31 January 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,7. 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to an amendment filed 31 January 2003 in paper number 11 in which claims 9, 21, 30 and 31 were amended. Claims 9-11 and 21-35 are pending.

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 31 January 2003 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Specification

2. The amendment filed 31 January 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is underlined as follows: On page 6, lines 22-23, “the specimen 34 is held down by a clamp mechanism 40 in a fixed orientation” and lines 26-27, “Other clamping mechanisms may be used to hold down the specimen in a fixed orientation such as meshes or a membrane overlay...” Applicant argues that this is not new matter as evident by the clamping mechanisms described in this paragraph and shown in the figures. However, in the original specification, there was no mention that the clamping mechanisms keep the specimen oriented in a fixed way. In fact, this paragraph further states “the use of a membrane or mesh may be preferable since the specimen 34 may be moved under the membrane” which teaches away from the specimen being held down in a fixed orientation.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-12, 21-24 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 9, 21 and 30, the applicant has added the limitation "in a fixed orientation" which is not supported by the specification as originally filed. In the original specification, there was no mention that the clamping mechanisms keep the specimen oriented in a fixed way. In fact, on page 6, lines 28-29 state "the use of a membrane or mesh may be preferable since the specimen 34 may be moved under the membrane" which teaches away from the specimen being held down in a fixed orientation. The dependent claims inherit the deficiencies of the claims from which they depend.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25-27 and 30-33 are under 35 U.S.C. 102(b) as being anticipated by Atwood et al., U.S. Patent No. 5,675,700.

Atwood et al. disclose a holder and method for imaging excised tissue comprising the steps of providing a container (figs. 1 and 2) having a surface/window (14) for placement of said excised tissue (12); restraining said excised tissue in said container against said surface in a fixed orientation (column 8, line 55) wherein said restraining step is carried out with the aid of one or more members (24), which represent fingers, extending into said container onto said excised tissue; each of said fingers has a spring (28) biasing the finger to hold said excised tissue upon said surface/window; and imaging said specimen through the surface/window (column 6, lines 7-10).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9-10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly, U.S. Patent No. 3,510,194 in view of Ornstein et al., U.S. Patent No. 4,545,831.

Regarding claims 9 and 21, Connelly discloses an apparatus (fig. 4) for imaging a specimen having a refractive index comprising a tray (42) upon which a specimen (41) is disposed; a means for clamping (44) said specimen upon said tray in a fixed orientation wherein

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the means for clamping is a finger; and optics (column 3, line 56, in so far as a microscope has optics) directed toward said specimen through a cover (40). Connelly discloses the claimed invention except for the specimen being excised tissue, the optics directed through a portion of said tray, and the tray containing an immersion media having a refractive index matching the index of said excised tissue. Ornstein teaches in fig. 4B a specimen (9), which is excised tissue, within an immersion media (18 and 27 – which are both curable polymer mediums with the same refractive index) having a refractive index matching the refractive index of the specimen (column 5, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add an immersion media to the system of Connelly to match the index of refraction of the specimen as suggested by Ornstein to give a very high quality image (column 5, lines 31-33, Ornstein). Ornstein further teaches the specimen on a clear tray (16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tray of Connelly transparent so the specimen can be viewed by inverted microscope systems. Additionally, Official Notice is taken that tissue, including excised tissue, are common specimens for microscopic examination (as evidenced by Ornstein) and it would have been obvious to one of ordinary skill in the art at the time the invention was made to view excised tissue with this system to determine the tissue's microscopic properties.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al., as applied to claim 9 above, and further in view of Tomimatsu, U.S. Patent No. 5,870,23.

Connelly in view of Ornstein et al., as applied to claim 9 above, disclose the claimed invention except for discloses a means disposed between said tray and said optics which presents a medium between said tray and said optics optically coupling said optics to said tray. In fig. 2, Tomimatsu teaches a means (14) disposed between said tray (12) and said optics (13) which presents a medium (14a) between said tray and said optics optically coupling said optics to said tray (column 3, lines 31-34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the means of Tomimatsu to the system of Connelly in view of Ornstein et al. to correct for spherical aberrations (column 2, lines 44-47).

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al., as applied to claim 9 above, and further in view of Atwood et al.

Connelly in view of Ornstein et al., as applied to claim 9 above, disclose the claimed invention except for having indicia applied to said tray for identification of said specimen disposed therein. Atwood et al. discloses indicia applied to a tray (figs. 1 and 2) for identification of the specimen disposed therein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tray of Connelly in view of Ornstein et al. to help keep the specimens in order and easily tracked.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al., as applied to claim 21 above, and further in view of Hauser, U.S. Patent No. 4,159,875.

Connelly in view of Ornstein et al., as applied to claim 21 above, disclose the claimed invention except for wherein each of said fingers has a spring biasing the finger. Hauser teaches a specimen holder with a spring (13a and 13b) biasing the finger. It would have been obvious to add a spring biasing the fingers of Connelly in view of Ornstein et al. to provide resilient properties to the finger so as not to damage the specimen while holding it in place.

12. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al., as applied to claim 9 above, and further in view of Foote, U.S. Patent No. 1,002,910.

Connelly in view of Ornstein et al., as applied to claim 9 above, disclose the claimed invention except for wherein said clamping means has a mesh or membrane capable of holding said specimen upon said tray. Foote discloses a clamping means that has a mesh (10, column 2, lines 78-83, where the pliable sheet is cloth) or membrane (10, column 2, lines 78-83, where the pliable sheet is paper) capable of holding a specimen upon a tray (fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tray of Tomimatsu in view of Connelly and Ornstein et al. to make the clamping means a mesh or a membrane as suggested by Foote to be easily adaptable for clamping specimens of various shapes and sizes.

13. Claims 25-26 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly, in view of Tomimatsu.

Regarding claims 25-26 and 30-32, Connelly discloses a holder and method for imaging a specimen comprising the steps of providing a container (figs. 1 and 2) having a surface (10) for placement of said specimen (23); restraining said specimen in said container against said surface in a fixed orientation (column 3, lines 50-51) wherein said restraining step is carried out with the aid of one or more members (21), which represent fingers, extending into said container; and imaging said specimen through the cover (13) of said container (column 3, lines 62-63).

Connelly discloses the claimed invention except for the specimen being excised tissue and imaging is through at least part of said surface or a window of said container. Tomimatsu teaches a microscopic system (figs. 2,4,6) wherein a specimen (12) in a transparent container (11) is imaged on either side of the container, which are windows. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make both container surfaces of Connelly transparent, or windows, to image the specimen with different microscopy systems. Further, Official Notice is taken that tissue, including excised tissue, are common specimens for microscopic examination and it would have been obvious to one of ordinary skill in the art at the time the invention was made to view excised tissue with this system to determine the tissue's microscopic properties.

Regarding claim 33, Connelly further discloses wherein said restraining step further comprises the step of biasing each of said fingers to restrain said tissue against said surface (in so far as each finger will be moved, or biased, slightly when pressing against the sample).

14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Tomimatsu, as applied to claim 25 above, and further in view of Hauser.

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Connelly in view of Tomimatsu, as applied to claim 25 above, disclose the claimed invention except for wherein each of said fingers has a spring biasing the finger. Hauser teaches a specimen holder with a spring (13a and 13b) biasing the finger. It would have been obvious to add a spring biasing the fingers of Connelly in view of Tomimatsu to provide resilient properties to the finger so as not to damage the specimen while holding it in place.

15. Claims 28-29 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly, in view of Tomimatsu, as applied to claims 25 and 30 above, and further in view of Foote, U.S. Patent No. 1,002,910.

Connelly, in view of Tomimatsu, as applied to claims 25 and 30 above, disclose the claimed invention except for wherein said clamping member/restraining step has a mesh or membrane capable of holding said specimen upon said surface/window. Foote discloses a clamping member/restraining step that has a mesh (10, column 2, lines 78-83, where the pliable sheet is cloth) or membrane (10, column 2, lines 78-83, where the pliable sheet is paper) capable of holding a specimen upon a surface/window (fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surface/window of Connelly, in view of Tomimatsu to make the clamping member a mesh or a membrane as suggested by Foote to be easily adaptable for clamping specimens of various shapes and sizes.

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Response to Arguments

16. Applicant's arguments with respect to claims 9-11, 21, and 30 have been considered but are moot in view of the new ground(s) of rejection.

17. After careful review of the claims, it is found that an obvious rejection is appropriate for claims 21-22, 25-29, and 31-33. The examiner regrets any inconvenience caused by this action.

18. Applicant's arguments filed 31 January 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that Foote is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Foote suggests a different way to hold a specimen in a specific place for viewing which is pertinent to the particular problem with which the applicant was concerned.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lee Fineman whose telephone number is (703) 305-5414. The examiner can normally be reached on Monday - Friday 7:30 - 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on (703) 305-0024. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.



LAF

June 29, 2003


MARK A. ROBINSON
PRIMARY EXAMINER